April 6, 2005

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novo nordisk®

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005N–0036:
Use of Color on Pharmaceutical Product Labels, Labeling and Packaging

Dear Sir/Madam:

Novo Nordisk Inc. appreciates the opportunity to provide comments to the above-captioned docket on Use of Color on Pharmaceutical Product Labels, Labeling and Packaging. Novo Nordisk is a pioneer in the promise of biotechnology and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as hemostasis management, growth hormone therapy, and hormone therapy for women.

February 3, 2005 Federal Register pp 5687-5689, FDA Question 3:

Are there drug products currently marketed that do not use color but should use color to aid in identification of the drug? If so, how should color be used?

Novo Nordisk® Comment:

As stated in the February 3, 2005 Federal Register notice, "color branding is a newly applied concept introduced by a single manufacturer of insulin products." As Novo Nordisk is the single manufacturer of insulin products mentioned in this notice, we believe it is important to share our experience and position on the potential benefits of the use of color on insulin product labeling. Our application for the use of color branding on insulin analog product packaging was approved by FDA on October 8, 2004.

1. History

Since the September 25, 1998 repeal of 21 CFR 429.12 which required black and white packaging of U-100 insulin, several prescription insulin analogs and insulin analog premixes have been launched in the US. In the preamble to the repeal, FDA acknowledged that the black and white packaging had limited usage and that there were no provisions made in these

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regulations for mixtures and insulin analogs. Thus, after the repeal, no regulation in the current Code of Federal Regulations prohibits the use of color.

During the latter half of the 1990's, there was an initiative to color code insulin products by the International Diabetes Federation (IDF), FDA and industry. **Color coding** is the systematic, standard application of color to aid in classification and identification of drug products. A color coding system allows people to remember a color and match it to its function. At the IDF meetings, colors were assigned to the human insulins and some analogs and this color coding was posted on the IDF website but is not updated and no further actions on color coding occurred. Additionally, there was acknowledgement that with the number of new insulin analogs anticipated to enter the market in the next few years, there would be difficulty in maintaining such a system to provide product differentiation of insulin analogs and premix insulin analogs.

Thus, when Novo Nordisk first began discussions with FDA in 2004 about the use of color in insulin product labeling, there was no defined plan or role in ownership of color coding for insulin products.

2. Novo Nordisk Experience

Novo Nordisk uses color on insulin packaging in 178 countries with no serious issues reported.

Until October 2004, the US was the only country that did not permit the use of color on packaging. With the growing family of US approved insulin products there was concern regarding the similarity in product labels.

When Novo Nordisk launched a new premixed insulin analog, NovoLog® Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin]), in 2002 in the U.S., the similarity of the name and packaging to an existing rapid-acting insulin analog, NovoLog® (insulin aspart [rDNA origin] injection), created the potential for product confusion and with attendant safety concerns. Medication errors and package mixups were occurring mainly at the pharmacy dispensing level and we believed the use of color on the labels might aid in distinguishing the products.

3. Proposal for Color Branding

During the discussions with FDA in 2004, Novo Nordisk proposed to use color branding for NovoLog® and NovoLog® Mix 70/30 packaging. **Color branding** allows the use of color on the labeling and packaging as an aid in differentiating one drug product from another. A specific color is not intended to indicate to a pharmacist or patient the action of the drug and is not a substitute for reading the label. Colors are chosen and managed by the individual sponsor and, as part of labeling, would require FDA approval before use.

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In summary, Novo Nordisk supports the use of **color branding** to aid in the identification of insulin analogs. Colors should be proposed by each manufacturer and approved by FDA.

Sincerely,

Novo Nordisk Inc.

Mary Ann McElligott, Ph.D.
Associate Vice President,
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